



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification⁶: A61F 2/06, A61M 29/00</p>	<p>A1</p>	<p>(11) International Publication Number: WO 97/09008</p> <p>(43) International Publication Date: 13 March 1997 (13.03.97)</p>
<p>(21) International Application Number: PCT/US96/14281</p> <p>(22) International Filing Date: 6 September 1996 (06.09.96)</p> <p>(30) Priority Data: 08/525,989 8 September 1995 (08.09.95) US</p> <p>(71) Applicant: MEDTRONIC, INC. [US/US]; 7000 Central Avenue N.E., Minneapolis, MN 55432 (US).</p> <p>(72) Inventors: FORGARTY, Thomas, J.; 3270 Alpine Road, Portola Valley, CA 94028 (US). LENKER, Jay, A.; 11195 Hooper Lane, Los Altos, CA 94024 (US). COY, Brian, J.; 1217 Gronwall Lane, Los Altos, CA 94024 (US). WILL, Allan, R.; 23 Belbrook Way, Atherton, CA 94027 (US). FREISLINGER, Kirsten; 545 University Avenue, Menlo Park, CA 94025 (US).</p> <p>(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew L.L.P., 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: METHOD AND APPARATUS FOR CONFORMABLY SEALING PROSTHESES WITHIN BODY LUMENS</p>		
<p>(57) Abstract</p> <p>A tubular prosthesis (10) is implanted at a target location within a body lumen by trans-luminal placing and embedding an expansible prosthesis body within a sealing layer (14). The sealing layer occludes at least a circumferential band within an interface region between the prosthesis body and the inner wall of the body lumen, thus providing for blockage of body lumen flow past the prosthesis. The sealing layer may be introduced prior to or simultaneously with the prosthesis body. A tubular prosthesis may be implanted in blood vessels, particularly to protect aneurysms.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

**METHODS AND APPARATUS FOR CONFORMABLY SEALING
PROSTHESES WITHIN BODY LUMENS**

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to methods and apparatus for the endoluminal placement of tubular prostheses, such as grafts, stents, and other structures. More particularly, the present invention relates to the implantation of luminal prostheses in a sealing layer within a body lumen.

Vascular aneurysms are the result of abnormal dilation of a blood vessel, usually resulting from disease and/or genetic predisposition which can weaken the arterial wall and allow it to expand. While aneurysms can occur in any blood vessel, most occur in the aorta and peripheral arteries, with the majority of aortic aneurysms occurring in the abdominal aorta, usually beginning below the renal arteries and often extending distally into one or both of the iliac arteries.

Aortic aneurysms are most commonly treated in open surgical procedures where the diseased vessel segment is bypassed and repaired with an artificial vascular graft. While considered to be an effective surgical technique, particularly considering the alternative of a usually fatal ruptured abdominal aortic aneurysm, conventional vascular graft surgery suffers from a number of disadvantages. The surgical procedure is complex and requires experienced surgeons and well-equipped surgical facilities. Even with the best surgeons and equipment, however, the patients being treated frequently are elderly and weakened from cardiovascular and other diseases, reducing the number of eligible patients. Even for eligible patients, conventional aneurysm repair surgery performed prior to rupture has a relatively high mortality rate, usually from 2% to 10%.

Morbidity related to the conventional surgery includes myocardial infarction, renal failure, impotence, paralysis, and other conditions. Additionally, even with successful surgery, recovery can take several weeks and often requires a lengthy hospital stay.

In order to overcome some or all of these drawbacks, endovascular graft placement procedures for the treatment of aneurysms have been proposed. Generally, such endovascular procedures will deliver a radially compressed graft intravascularly to the aneurysm. The graft is then expanded *in situ*, either by releasing a self-expanding graft or by internally expanding a malleable graft (e.g. using a balloon catheter) to protect the aneurysm. Usually, the vascular graft will comprise both a frame and a liner, where the frame provides the necessary mechanical support and the liner provides the necessary blood barrier.

While highly promising, the endovascular placement of vascular grafts is problematic in several respects. In contrast to surgically implanted grafts, which are sutured in place, endovascularly placed grafts can be difficult to anchor and position. Reliance on the outward spring-force of a self-expanding graft is not always sufficient. Malleable grafts, in contrast, may be easier to initially anchor but may be less able to expand and contract with the blood vessel during the continuous pulse of the patient. While the use of hooks or barbs for anchoring grafts into the blood vessel wall has been proposed, such devices can be traumatic and can loosen from the blood vessel wall over time. As the anchoring of the vascular prosthesis loosens over time, blood can begin to bypass the graft and flow into the region between the graft and the blood vessel wall. Such misdirected blood flow into the aneurysm can again expose the patient to risk of aneurysm rupture and its consequences. Additionally, heretofore, it has been difficult to radially reinforce both self-expanding and malleable graft structures to help in maintaining the structures within the blood vessel.

Referring to Prior Art Figs. 1-3, the problem of blood flow leakage past a graft structure 10 implanted within

the region of an aneurysm A in a blood vessel BV is illustrated. While the graft 10 may be adequately anchored on each side of the aneurysm A, as illustrated in Fig. 1, over time the inner surface of the blood vessel lumen can partially
5 separate from the outer surface of the graft 10, as illustrated in Figs. 2 and 3. Such separations S can allow bypass blood flow into the region of the aneurysm A.

For these reasons, it would be desirable to provide improved luminal prostheses and methods for their implantation
10 which can overcome at least some of the difficulties described above. In particular, it would be desirable to provide intraluminal prostheses and methods for their implantation which would provide a generally fluid tight seal circumscribing at least one end of the prosthesis, and
15 preferably both ends or the entire length of the prosthesis, to prevent bypass blood or other fluid flow into the interstitial region between the inner wall of the body lumen and the outer surface of the prosthesis. In particular, it would be desirable if such improved prostheses and methods for
20 their implantation would provide for sealing of the prosthesis which would resist separating from the intraluminal wall in order to prevent such bypass flow in a long-term or permanent fashion after implantation of the prosthesis. In some cases, it will be desirable to provide methods which permit such
25 sealing implantation when using otherwise conventional prosthesis structures, such as vascular stents and grafts. In other cases, it will be desirable to provide improved prosthesis structures which incorporate features which provide for such sealing implantation when implanted using methods
30 according to present invention.

2. Description of the Background Art

The delivery of polymerizable fluids to body tissues for a variety of purposes, including "paving" of vascular
35 lumens, has been proposed. See, for example, PCT Publications WO 94/24962 and WO 94/21324, and U.S. Patent No. 5,092,841. Luminal prostheses which are delivered in a compliant state and hardened *in situ* by exposure to heat, radiation, or other

polymerization-initiating event are described in U.S. Patent Nos. 5,344,444; 5,334,201; and 5,100,429; EP 521573; and de Vries et al., "Instant Tubular Prosthesis: A Totally New Concept," *International Congress VII Endovascular Interventions*, Phoenix, Arizona, February 1994. A fabric prosthesis which is secured to an inner vascular wall by a contact adhesive, such as cyanoacrylate, is described in U.S. Patent No. 4,577,631. The use of autologous fibrin glue for sealing porous, fabric grafts prior to open surgical implantation is described in Kjaergard and Weis-Fogh (1994) *Card. Surg.* 2:45-46. A tubular prosthesis having an annular cavity for receiving a plastic material to enlarge and anchor the prosthesis within a blood vessel is described in U.S. Patent No. 5,156,620. A tubular prosthesis having inflatable cuffs on each end is described in U.S. Patent No. 3,991,767. A tubular prosthesis having everted cuffs for receiving sutures is described in U.S. Patent No. 4,728,328. A tubular stent having hook-like projections over its outer surface is described in U.S. Patent No. 5,167,614. A tubular stent having a plurality of self-locking fingers extending outward from its outer surface is described in U.S. Patent No. 5,344,426. A fluid delivery catheter comprising concentric lumens in a balloon structure is described in U.S. Patent No. 5,295,962. A vascular prosthesis comprising two porous concentrically associated tubes with a helical spring enclosed therebetween is disclosed in U.S. Patent No. 4,130,904. A vascular prosthesis comprising a multilaminar tubular member is disclosed in U.S. Patent No. 5,354,329. Microporous materials suitable for the fabrication of prosthetic devices are described in U.S. Patent Nos. 3,890,107 and 5,348,788.

SUMMARY OF THE INVENTION

The present invention provides methods and apparatus for the transluminal positioning of tubular prostheses at a target location within a body lumen. The tubular prostheses are suitable for a wide variety of therapeutic uses, including stenting of the ureter, urethra, biliary tract, and the like. The devices and methods will also find use in the creation of

temporary or long-term lumens, such as the formation of fistulas. The present invention will find its greatest use, however, in the placement of endovascular grafts into blood vessels for the treatment of abdominal and other aneurysms, vascular stenoses, and the like.

According to the method of the present invention, a tubular prosthesis is delivered to the target site within the body lumen in a radially compressed configuration and is expanded *in situ* at the target location so that an exterior surface of the prosthesis engages an inner wall of the body lumen over an interface region therebetween. Radial expansion of the prosthesis may be effected in any conventional manner, including the use of a balloon catheter for expanding malleable prostheses, the release of compressed, self-expanding prostheses from suitable delivery catheters, and the like. The present invention particularly provides for expansion of the prostheses into a sealing layer which is disposed in or over at least a portion of the interface region.

The sealing layer may be disposed within substantially the entire interface region, or may be disposed over one or more discrete, circumferential bands within the interface region. Usually, the sealing layer will be disposed at least at each end of the tubular prosthesis in order to provide a barrier against the bypass leakage of fluid into portions of the interface region therebetween. Preferably, the sealing layer will occupy substantially the entire interface region.

The sealing layer may be composed of virtually any material which is biocompatible and capable of conforming to the interface region between the outer wall of the tubular prosthesis and the inner wall of the body lumen. Exemplary materials include gels, foams, adhesives, biological polymers, compliant sleeves, sponges, porous matrices and meshes, and the like. In some cases, the materials are initially present on the prosthesis or delivered in a fluid or semi-solid state to the interface region, and thereafter cured or hardened to achieve the final, desired geometry. Additionally, the

sealing layer may be composed of materials which expand *in situ* in order to fully conform to the geometry of the interface region, e.g. including materials such as hydrophilic gels, hydrophilic foams, and the like. An exemplary material for the sealing layer comprises a microporous mesh, particularly composed of silicone rubber and similar materials.

In a first particular aspect of the present invention, the sealing layer may be initially formed or disposed over at least a portion of the exterior surface of the tubular prosthesis prior to *in situ* expansion. In such cases, the tubular prosthesis will usually be pre-coated or covered with the material of the sealing layer prior to introduction of the prosthesis to the body lumen.

In a second particular aspect of the method of the present invention, the material of the sealing layer may be introduced in an initial step prior to introduction of the tubular prosthesis. Usually, a fluid delivery catheter will be employed to apply the sealing layer material in a fluid or semi-solid state over at least a portion of the interface region. The fluid delivery catheter is removed, and a prosthesis delivery catheter is then introduced to the target location. The prosthesis carried by the catheter may then be expanded *in situ* so that it engages and conforms to the material of the sealing layer.

Apparatus according to the present invention includes tubular prostheses comprising an expansible tubular frame having a sealing layer formed at least partially over an exterior surface thereof. The sealing layer may be formed of any of the materials described above.

The apparatus according to the present invention further includes a fluid delivery catheter comprising a catheter body having a proximal end and a distal end. An outer balloon and an inner balloon are disposed on the catheter near its distal end. The outer balloon is positioned over the inner balloon and includes a plurality of fluid delivery ports formed over its surface. The outer balloon is connected to a first lumen within the catheter body and can

receive a fluid or semi-solid sealing material therethrough. The inner balloon is connected to a second lumen within the catheter body and can receive an expansion medium therethrough. By first filling the outer balloon with the fluid or semi-solid sealing material, and thereafter expanding the inner balloon within the outer balloon, the sealing material is extruded outwardly through the fluid delivery ports in an annular layer over the inner surface of the luminal wall. The prosthesis may then be delivered to the body lumen and expanded so that it becomes embedded in the layer of sealing material. The sealing material hardens, optionally with the application of energy conforming to the exterior of the prosthesis and providing a substantially permanent anchor and barrier to the bypass of body fluid.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1-3 illustrate prior art implantation of a vascular prosthesis.

Fig. 4 is a cross-sectional view of a vascular prosthesis embedded in a sealing layer in the region of an aneurysm according to the present invention.

Fig. 5 is a cross-sectional view taken along line 5-5 of Fig. 4.

Fig. 6 is a cross-sectional view taken along line 6-6 of Fig. 4.

Fig. 7 illustrates a tubular prosthesis constructed in accordance with the principles of the present invention, in a radially compressed configuration.

Fig. 8 illustrates the tubular prosthesis of Fig. 7 in a radially expanded configuration.

Fig. 9 illustrates a bifurcated prosthesis constructed in accordance with the principles of the present invention.

Fig. 10 illustrates a fluid delivery catheter intended for the intraluminal delivery of a sealing material for use in the methods of the present invention.

Figs. 11A-11F illustrate a particular embodiment of the method of the present invention employing an initial

sealing material delivery step followed by a separate prosthesis implantation step.

Fig. 12 illustrates a first embodiment of a sealing sleeve intended for implantation at the bifurcation of the abdominal aorta into the left and right iliac arteries.

Fig. 13 is an alternate embodiment of a sealing sleeve for implantation at the bifurcation of the abdominal aorta into the right and left iliac arteries.

Fig. 14 illustrates the implantation of a vascular graft between a pair of sealing sleeves to treat an abdominal aortic aneurysm.

Fig. 15 illustrates an alternative anchoring of the vascular graft of Fig. 14 with a sealing sleeve which extends into the renal arteries.

Fig. 16 illustrates use of the vascular prosthesis of the present invention for sealing at each end of a previously implanted prosthesis.

Fig. 17 illustrates an alternative embodiment of the sealing prosthesis of the present invention.

Fig. 18 illustrates one end of a tubular prosthesis having a plurality of resilient tines which support a fabric sealing layer circumferentially thereabout.

Fig. 19 is a detailed section view taken along line 19-19 in Fig. 18.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides methods and apparatus for the implantation of tubular prostheses in body lumens. The present invention will find use in the placement of any type of graft or stent in a wide variety of body lumens, including blood vessels, the ureter, the urethra, the biliary tract, and the like. The methods and devices will also find use in the creation of temporary or long-term lumens, such as the formation of fistulas. The preferred use of the present invention, however, is for the percutaneous placement of endovascular grafts and stents for the treatment of diseases of the vasculature, particularly aneurysms, stenoses, and the like.

Tubular prostheses according to the present invention will comprise a tubular body having a radially compressed configuration and a radially expanded configuration. The tubular prosthesis is introduced to a target size within the body lumen with the tubular body in its radially compressed configuration. After proper placement at the target location, the tubular body will be radially expanded, either by releasing the body to permit self-expansion or by applying a force to the body to cause radial expansion, as described in more detail below.

The tubular body of the prosthesis will typically have a length in the range from about 30 mm to 500 mm, usually from 80 mm to 200 mm, with an expanded diameter in the range from 2 mm to 45 mm, usually being in the range from 5 mm to 25 mm, and a compressed diameter in the range from 1 mm to 9 mm, usually from 3.5 mm to 7 mm. These dimensions are particularly suitable for graft structures intended for treating vascular aneurysms.

The tubular body of the prosthesis can have any configuration normally employed for such medical prostheses, including sleeves, lattices, counter-wound helices, braids, slotted tubes, and the like. The tubular body may be linear (i.e., in the form of a single cylindrical tube with a first end, a second end, and a lumen therebetween), or branched (i.e., in the form of a "Y" with a first end, a pair of branched, second ends, and lumens therebetween, such as those typically used for aortic aneurysms extending from the abdominal aorta into the iliac arteries), or in any other configuration used for vascular and other luminal prostheses now or in the future.

Configurations suitable for use as the tubular body component of the tubular prostheses of the present invention are well described in the patent and medical literature. See, for example, U.S. Patent Nos. 5,219,355; 5,211,658; 5,104,399; 5,078,726; 4,820,298; 4,787,899; 4,617,932; 4,562,596; 4,577,631; and 4,140,126, the full disclosures of which are incorporated herein by reference. Preferred constructions for the tubular body of the present invention are described in

copending Application Serial Nos. 08/255,681, filed on June 8, 1994, and 08/414,995, filed on March 31, 1995, the full disclosures of which are incorporated herein by reference.

5 The tubular body of the prosthesis can be composed of a wide variety of biologically compatible materials, including metals, organic polymers, and combinations thereof. The materials can further be selected or modified to provide a variety of secondary characteristics, such as shape memory,
10 drug delivery, bioabsorbability, radiopaqueness, and the like. Frequently, the tubular body will be composed of two or more different materials in order to provide desired characteristics to the body. For example, it may be desirable to fabricate the tubular body both from organic polymers,
15 which can provide flexibility and impermeability, and from metallic elements which can provide self-expansion, resilience, and structural integrity. Such different materials can be incorporated in a variety of ways. For example, different interwoven helices, braids, or other
20 elements can be composed of different materials. Alternatively or additionally, the interwoven elements can themselves be composed of two or more materials, particularly when the flat ribbons are composed of multiple individual filaments. Additionally, different materials can be laminated
25 over within the body of the tubular prosthesis to provide for desired properties. Preferred materials of construction include tantalum, titanium, nickel-titanium alloy (Nitinol®), polyester (e.g. polyethylene terephthalate), and polytetrafluoroethylene (PTFE).

30 The present invention particularly provides for a sealing layer to be disposed over a tubular prosthesis body which has been implanted in the patient's body lumen. The sealing layer will provide for an essentially fluid-tight seal over at least one circumferential band disposed in an
35 interface region between the exterior surface of the tubular prosthesis body and an inner wall of the body lumen. Often, the sealing layer will fill or cover substantially the entire interface region, but such complete coverage will not always

be necessary. Sometimes, it will be sufficient to form only a single band of the sealing layer material at one or both ends of a linear prosthesis body, or at one, two, or three ends of a bifurcated prosthesis body.

5 In addition to at least partially occluding the interface region between the tubular prosthesis body and the body lumen, the sealing layer will usually serve in addition to anchor the prosthesis body in the patient's body lumen. Thus, the sealing layer may immediately, or over time, assume
10 a generally a solid (although preferably compliant) configuration which both blocks fluid flow (e.g. prevents incursion of fluid into an aneurysm which is being treated with a vascular prosthesis) and which also firmly anchors the prosthesis at the target location. Optionally, an adhesive
15 may be placed over at least a portion of the interface between the sealing layer and the interior of the blood vessel wall.

The sealing layer which is eventually formed will have a thickness sufficient to provide both the occlusion and anchoring functions described above. The thickness of the
20 sealing layer will generally be between about 0.5 mm to 5 mm, usually from 1 mm to 3 mm, depending on the nature of both the sealing layer material and the tubular prosthesis body. For example, gels and foams will typically be thicker than will be adhesives, as described in more detail below.

25 The sealing layer may be composed of a wide variety of materials, usually being in the form of a gel, foam, sponge, adhesive, biological polymer, compliant sleeve, microporous mesh, or the like. The material may initially be in a fluid (liquid) or semi-solid state, where the material
30 may be at least partially hardened after introduction to the target location within the body lumen and *in situ* expansion of the tubular prosthesis body. Additionally, the sealing layer material may be hydrophilic, particularly being in the form of a hydrophilic gel or foam, so that it may absorb body fluids
35 to enhance occlusion of the interface region. Such hydrophilic materials are often highly compliant and conformable and are particularly suitable for conforming to changes in the shape of the luminal wall which may occur over

time. In contrast to the fluid and semi-solid materials, the sealing layer may also be in the form of a resilient or elastomeric sleeve which partially or fully occupies the interface region. The elastomeric sleeve can be a tubular member, such as an extruded elastomer, which is placed over the tubular prosthesis body before expansion. Alternatively, the sleeve could be a self-expanding mechanical assembly formed from a compliant fabric or other material, with internal springs or other mechanisms for providing the desired resilience and thickness.

Suitable gel materials include hydrogels, particularly acrylates and acrylamides, such as polyacrylamide, polyhydroxyethyl methacrylate, and the like. These materials, which will typically be applied to the exterior surface of the tubular body of the prosthesis prior to expansion, may be formulated to provide for both surface adhesion and swellability. These materials may be applied either in circumferential rings at either single or multiple ends of the tubular graft structure, or to cover substantially the entire outer surface of the tubular prosthesis body.

Hydrophilic sealing cuffs which absorb water and expand to seal about the periphery of the prosthesis body can be fabricated in a number of ways. For example, a water permeable membrane can be made from a woven or knitted material composed of polyester, polyethylene, or polyethyleneterephthalate (PTFE). A suitable woven PTFE is available under the tradename GORTEX®. A hydrogel can be placed inside the water permeable membrane. Suitable hydrogels include polyethylene glycol (PEG)/poly-hydroxyethyl methacrylate (pHEMA), commercially available under the tradename HYDRON®.

Suitable foams include polyurethanes (e.g. open cell polyurethanes), silicones, and the like. Such foams will generally be applied prior to implantation of the tubular prosthesis body, typically using a fluid delivery catheter as described in more detail below.

Suitable adhesives include acrylates, epoxies (including two-part curable epoxies), fibrin-based adhesives,

and other specialized adhesives. An exemplary adhesive is a crystalline polymer which changes from a non-tacky crystalline state to an adhesive gel state when the temperature is raised from room temperature to body temperature. Such material is available under the trade name Intillemer[®] adhesive, available from Landec Corp.

Suitable biological polymers include proteins, such as collagen, fibrin, fibrinogen, elastin, and the like, which can be either formed over the tubular prosthesis body prior to implantation, or delivered to the target site in the body lumen prior to delivery of the tubular prosthesis body. Specific examples of the proteins include fibrin-based glues which include both a fibrinogen component and a thrombin component to produce fibrin.

An exemplary material for the compliant sleeve is microporous silicone rubber, such as that described in U.S. Patent Nos. 3,890,107 and 5,348,788, the full disclosures of which are incorporated herein by reference. Such materials may be molded or machined into sleeves which are disposed between the exterior of the prosthesis and the interior of the luminal wall. The sleeves may be pre-loaded over the tubular prosthesis (i.e., prior to delivery and *in situ* expansion of the combined prosthesis and sleeve) or may be delivered to and implanted at the target location in the body lumen prior to delivery and *in situ* expansion of the prosthesis.

Referring now to Figs. 4-6, implantation of a vascular prosthesis 10 within an aneurysm A in a blood vessel BV will be described. The prosthesis 10 includes a tubular prosthesis body 12, which is illustrated as a linear, cylindrical prosthesis. The prosthesis body 12 is implanted within a sealing layer 14 which conforms to the exterior surface of the prosthesis body 12 and which substantially fills and occludes the annular interface region between the outer surface of the prosthesis body 12 and the inner wall of the blood vessel lumen at each end of the aneurysm A, as best seen in the cross-sectional views of Figs. 5 and 6. The sealing layer 14 may have been applied within the blood vessel lumen prior to implantation of the tubular prosthesis body 12,

or may have been introduced over the exterior of the prosthesis body prior to implantation.

Referring now to Figs. 7 and 8, a prosthesis 20 comprises a tubular prosthesis body 22 (which may be self-expanding or malleable, as generally described above) having a sealing layer 24 formed over its exterior surface. The sealing layer 24 may have any of the forms described above, and will be formed over the prosthesis body 22 prior to implantation. Thus, the sealing layer 24 will be configured to radially expand together with the prosthesis body 22 (optionally by application of an internal expansion force, e.g. applied from an internal balloon catheter), as illustrated in Fig. 8. After radial expansion, the sealing layer 24 will still be sufficiently resilient and conformable to provide for the occlusion of the interface region between the prosthesis and the inner wall of the body lumen.

An exemplary branched prosthesis having a "Y"-configuration and constructed in accordance with the principles of the present invention is illustrated in Fig. 9. The prosthesis body 32 may be of conventional construction, but includes a circumferential band of sealing material at each of the ends thereof. The prosthesis could also have a cross or "X" - configuration where bands of sealing material are provided at one or more of the four branches (not illustrated).

Referring now to Fig. 10, a catheter 40 designed to deliver fluid or semi-solid phase sealants to interior of a body lumen will be described. Catheter 40 includes catheter body 42 having a distal end 44 and a proximal end 46. An outer balloon 48 and inner balloon 50 are coaxially mounted near the distal end 44 of the catheter body 42. The outer balloon 48 is connected through a lumen in body 42 to a first port 52 in proximal housing 54 to receive the fluid or semi-solid phase sealant. The inner balloon 50 is connected through a second lumen in catheter body 42 to receive inflation medium through a second port 56 in the proximal hub 54. In this way, a fluid or semi-solid sealant may first be delivered to the interior of outer balloon 48 over the

inner balloon 50. By then inflating the inner balloon 50, the sealant may be expelled outward through a plurality of fluid delivery ports 58 disposed substantially uniformly over the outer cylindrical surface of the outer balloon 58.

5 Preferably, the outer balloon 58 will be formed from a non-compliant material, such as polyethyleneterphthalate. The inner balloon 50 is preferably formed from an elastomeric material, such as silicone rubber latex rubber, or polyurethane. The catheter body 42 is configured to be
10 introduced over a movable guidewire, including guidewire port 60 extending therethrough.

Referring now to Figs. 11A-11F, a method for delivering a vascular prosthesis according to the present invention will be described. Initially, fluid delivery
15 catheter 40 is introduced to a region of an aneurysm A in blood vessel BV over a guidewire GW, as illustrated in Fig. 11A. The outer balloon 48 is then at least partially filled with a fluid or semi-solid sealant S, as illustrated in Fig. 11B. The inner balloon 50 is then expanded to expel the
20 sealant through the ports 58 into the region of aneurysm A, as illustrated in Fig. 11C.

After sufficient sealant S has been introduced to the interface region along the inner surface of the blood vessel wall, the catheter 40 will be withdrawn, leaving the
25 sealant S in place, as illustrated in Fig. 11D. A graft delivery catheter 60 may then be introduced to the blood vessel BV so that a tubular prosthesis body 62 is positioned within the sealant S, as illustrated in Fig. 11E. As illustrated in Fig. 11E, the prosthesis body 62 is malleable
30 and expanded by an internal balloon 64. It will be appreciated, however, that the prosthesis body 62 could be in the form of a self-expanding (resilient) tube which is released from radial constraint by a different delivery catheter. Other delivery techniques, such as axial
35 contraction to cause radial expansion of the prosthesis, are also known and could be employed with the present invention. In any case, after the prosthesis body 62 is expanded and/or released, it will compress radially outwardly against the

sealant material S to compress and conform the sealant into the interface region, as illustrated in Fig. 11F. Sealant material may then at least partially harden (optionally by applying energy to cure the material) to provide both for occlusion of the interface region (to prevent bypass flow of blood into the aneurysm A) and also to anchor the prosthesis body 62 in place.

Referring now to Fig. 12, a sealing layer in the form of a bifurcated tube 100 includes a trunk segment 102 and a pair of leg segments 104 and 106. Of the sleeve 100 will be composed of a resilient, preferably "spongy" material which can be introduced into the base of the abdominal aorta so that the legs 104 and 106 into the right and left iliac arteries, respectively. Preferably, each of the trunk 102 and right and left legs 104 and 106 will comprise structure, such as a self-expanding spring 108, which will radially expand the sleeve at each of its openings so that the sleeve will self-anchor in the aorta and iliac arteries. Fig. 13 shows an alternative 120 which is generally similar to the sleeve 100, except that self-expanding tubular elements 122, 124, and 126, are provided in the trunk 128, leg 130, and leg 132 respectively. These self-expanding tubes are generally similar to the tubular prosthesis structures described previously and provide the necessary mechanical support to anchor the sleeve 120 at the bifurcation of the abdominal aorta into the iliac arteries. The sleeve 120, however, will not itself form the necessary vascular graft over the aneurysm, but rather will form a resilient anchor at the base of the aorta for subsequent implantation of a separate vascular graft, as described in below in connection with Figs 14 and 15. The preferred material for the sleeves 100 and 120 will be micro porous silicone rubber, as described above.

Referring now to Fig. 14, the sleeve 100 or 120 can be implanted at the base of an abdominal aortic aneurysm AAA so that the trunk portion 102 or 128 extends into the aorta and the leg portions 104 or 130 and 106 or 132 extend into the right iliac RI and left iliac LI, respectively. An upper sleeve anchor 140 will be implanted above the aneurysm AAA and

below the renal arteries RA. The sleeve 140 will be composed of a similar resilient material, preferably silicone rubber, and will usually be self-expanding so that it can be initially placed at the desired location. A vascular prosthesis P which
5 may be any self-expanding or expandable vascular graft as described previously, may then be implanted between the upper sleeve 140 and base sleeve 100 or 120. In this way, a simple, linear prosthesis can be used to treat an aortic aneurysm AAA. Optionally, additional prosthesis (not shown) could be
10 implanted in each of the legs 104/130 and 106/132 of the sleeve in order to further anchor the sleeve and provide desired support within the iliac arteries.

As an alternative to the upper sleeve 140, a sleeve 150 (Fig. 15) could be provided having side branches 152 and
15 154 which extend into the renal arteries RA. Such a sleeve would be particularly desirable for aneurysms which extend upwardly and approach the renal arteries.

The tubular prostheses of the present invention will also find use in sealing at one or more ends of a previously
20 implanted prosthesis as shown in Fig. 16. There, a prosthesis 200 (which may be a conventional graft or stent or may itself be a "sealing" prosthesis according to the present invention) is initially implanted in an aneurysm A. Over time, the length of the aneurysm may increase, creating paths at one or
25 both ends for blood to bypass the prosthesis into the aneurysm. This situation may be corrected by implanting additional sealing prosthesis 202 which are constructed in accordance with any of the designs described herein. The prostheses 202 will be disposed inside each end of the initial
30 or central prosthesis 200 into the adjacent lumen of the blood vessel. The prostheses 202 are shown to include body 204 and sealing layer 206, and the sealing layer is able to conform to the end transition between the prosthesis 200 and the blood vessel wall, providing an effective seal against blood bypass
35 and a further anchor of the prosthesis 200 in place. While particularly useful for post-placement sealing, the method of introducing the sealing prostheses into one or more ends of a

primary graft would also be useful at the time the primary graft is first introduced.

An alternative sealing layer construction is shown in Fig. 17. A prosthesis 250 comprises a tubular body 252 and an inner liner 254. The tubular body comprises a plurality of spring-like fingers 256 which support an outer liner 258 radially outward. The inner liner 254 and outer liner 258 may be composed of the same or different materials, typically being polyester, polytetrafluoroethylene (PTFE), polyurethane, non-woven fabric, polymeric sheet material or the like. Generally the liners should present a barrier to blood flow therethrough. The spring-like fingers will allow the outer liner 258 to conform to the inner wall of the blood vessel to provide sealing as described generally above.

Figs. 18 and 19 show yet another alternative construction for a sealing layer according to the present invention. The sealing layer comprises a fabric or membrane layer 300 which opens conically about an end 302 of a prosthesis 304. The layer 300 is shown to be supported by a plurality of tines 306 which are connected to the end of the prosthesis 304. As illustrated, the tines 306 are formed integrally as part of a metallic framework 310 of the prosthesis, but it will be appreciated that the tines could be welded or otherwise attached to the framework. In the embodiment of Figs. 17 and 18, a fabric liner 316 is shown to be folded from the interior of the prosthesis back into and over a V-shaped cavity 318 defined by the tines 306. It will be appreciated that, upon deployment in a blood vessel, the layer 300 will engage and conform to the interior surface of the vessel and the layer will seal the end of the prosthesis 304 to inhibit by-pass blood flow. It will be further appreciated that the sealing layer 300 could be formed in a variety of other specific designs, including an unsupported or partially supported fabric or membrane which is held open to seal against the blood vessel wall by the blood flow itself which applies pressure within the cavity 318.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

5

WHAT IS CLAIMED IS:

1 1. In a method for implanting a tubular prosthesis
2 in a body lumen of the type wherein the tubular prosthesis is
3 expanded *in situ* so that an exterior surface of the prosthesis
4 engages an inner wall of the body lumen over an interface
5 region, the improvement comprising expanding the tubular
6 prosthesis, in a sealing layer disposed in at least a portion
7 of the interface region.

1 2. A method as in claim 1, wherein the tubular
2 prosthesis has at least a first end, a second end, and a lumen
3 therebetween, and wherein the sealing layer is disposed over
4 at least one circumferential band within the interface region.

1 3. A method as in claim 2, wherein the sealing
2 layer is disposed within substantially the entire interface
3 region.

1 4. A method as in claim 1, wherein the tubular
2 prosthesis has a first end and a pair of branched second ends
3 with lumens therebetween, and wherein the sealing layer is
4 disposed over at least a circumferential band within the
5 interface region near the first end.

1 5. A method as in claim 4, wherein the sealing
2 layer is disposed over substantially the entire interface
3 region.

1 6. A method as in claim 1, wherein the sealing
2 layer is selected from the group consisting of gels, foams,
3 sponges, adhesives, biological polymers, microporous meshes,
4 and a self-expanding mechanical assembly.

1 7. A method as in claim 6, wherein the sealing
2 layer is a microporous silicone rubber mesh.

1 8. A method as in claim 1, wherein the sealing
2 layer is disposed over at least a portion of the exterior
3 surface of the tubular prosthesis prior to *in situ* expansion.

1 9. A method as in claim 1, wherein the improvement
2 further comprises introducing the sealing layer within the
3 body lumen prior to *in situ* expansion of the tubular
4 prosthesis.

1 10. A method for implanting a tubular prosthesis in
2 a body lumen, said method comprising:
3 introducing a sealing layer over an interface region
4 along an interior wall of the body lumen; and
5 expanding a tubular prosthesis within the body lumen
6 so that the sealing layer provides a seal between an exterior
7 surface of the tubular prosthesis and the interior wall of the
8 body lumen.

1 11. A method as in claim 10, wherein the sealing
2 layer introducing step comprises transluminally positioning a
3 distal end of a catheter at the interface region within the
4 body lumen and applying a fluid phase sealing material from
5 the distal end of the catheter over said interface region.

1 12. A method as in claim 11, wherein the fluid
2 phase sealing material is selected from the group consisting
3 of gels, foams, adhesives, and biological polymers.

1 13. A method as in claim 10, wherein the tubular
2 prosthesis expanding step comprises transluminally positioning
3 a distal end of a catheter near the sealing layer within the
4 body lumen and releasing a radially constrained,
5 self-expanding prosthesis within said sealing layer.

1 14. A method as in claim 10, wherein the tubular
2 prosthesis expanding step comprises transluminally positioning
3 a distal end of a catheter near the sealing layer within the
4 body lumen and inflating a balloon on the catheter to expand
5 an at least partially malleable prosthesis within said sealing
6 layer.

1 15. An improved tubular prosthesis of the type
2 including an expansible tubular frame, wherein the improvement
3 comprises a sealing layer formed over at least a portion of
4 the exterior surface of the tubular frame, said sealing layer
5 being expansible together with the tubular frame and capable
6 of forming a liquid-resistant barrier over an annular exterior
7 segment of the frame after expansion when implanted in a body
8 lumen.

1 16. An improved tubular prosthesis as in claim 15,
2 wherein the expansible tubular frame is at least partly
3 resilient so that it can be released from radial constraint to
4 assume a large diameter configuration.

1 17. An improved tubular prosthesis as in claim 15,
2 wherein the expansible tubular frame is at least partly
3 malleable so that it can be radially expanded by application
4 of an internal expansion force.

1 18. An improved tubular prosthesis as in claim 15,
2 wherein the sealing layer is selected from the group
3 consisting of gels, foams, adhesives biological polymers,
4 sponges, compliant sleeves, microporous meshes, and a self-
5 expanding mechanical assembly.

1 19. An improved tubular prosthesis as in claim 18,
2 wherein the sealing layer is a microporous silicone rubber
3 mesh.

1 20. An improved tubular prosthesis as in claim 15,
2 wherein the sealing layer is disposed over at least a
3 circumferential band of the exterior surface of the tubular
4 frame.

1 21. An improved tubular prosthesis as in claim 20,
2 wherein the sealing layer is disposed over substantially the
3 entire exterior surface.

1 22. A fluid delivery catheter, said catheter
2 comprising:

3 a catheter body having a proximal and a distal end,
4 and at least two lumens extending therebetween;

5 an outer balloon disposed near the distal end of the
6 catheter body and having fluid delivery ports formed therein,
7 said outer balloon being connected to receive a fluid from a
8 first of the lumens; and

9 an inner balloon disposed on the catheter body
10 within the outer balloon and connected to receive an inflation
11 medium from a second of the lumens, wherein expansion of the
12 inner balloon will expel fluid within the outer balloon
13 outwardly through the delivery ports.

1 23. A fluid delivery catheter as in claim 22,
2 wherein the outer balloon is non-compliant and the inner
3 balloon is elastic.

1 24. A fluid delivery catheter as in claim 23,
2 wherein the outer balloon has a generally cylindrical profile
3 when expanded and wherein the delivery ports are substantially
4 uniformly distributed over an outer cylindrical wall thereof.

1 25. A fluid delivery catheter as in claim 22,
2 wherein the fluid delivery ports have sufficient flow
3 resistance to inhibit fluid flow in the absence of internal
4 pressure provided by the inner balloon.

1 26. A method for delivering a fluid to an inner
2 wall of a body lumen, said method comprising:
3 positioning an outer balloon at a target site within
4 the body lumen;
5 at least partially filling the outer balloon with a
6 fluid material to be delivered; and
7 inflating an inner balloon within the outer balloon
8 to expel the fluid material through fluid delivery ports
9 formed in the outer balloon.

1 27. A method as in claim 26, wherein the body lumen
2 is a blood vessel and the target site is a location which is
3 to receive a tubular prosthesis.

1 28. A method as in claim 27, wherein the site is
2 proximate an aneurysm.

1 29. A method as in claim 26, wherein the outer
2 balloon is filled with a material selected from the group
3 consisting of gels, foams, adhesives, and biological polymers.

1 30. A method as in claim 29, wherein the outer
2 balloon is filled sufficient to engage its outer surface
3 against an interior wall of the body lumen without substantial
4 loss of fluid material through the delivery ports prior to
5 expansion of the inner balloon.

1 31. A method as in claim 30, wherein the inner
2 balloon is elastic and is inflated sufficiently to conform to
3 the inner wall of the outer balloon to expel substantially all
4 fluid through the delivery ports.

1 / 12

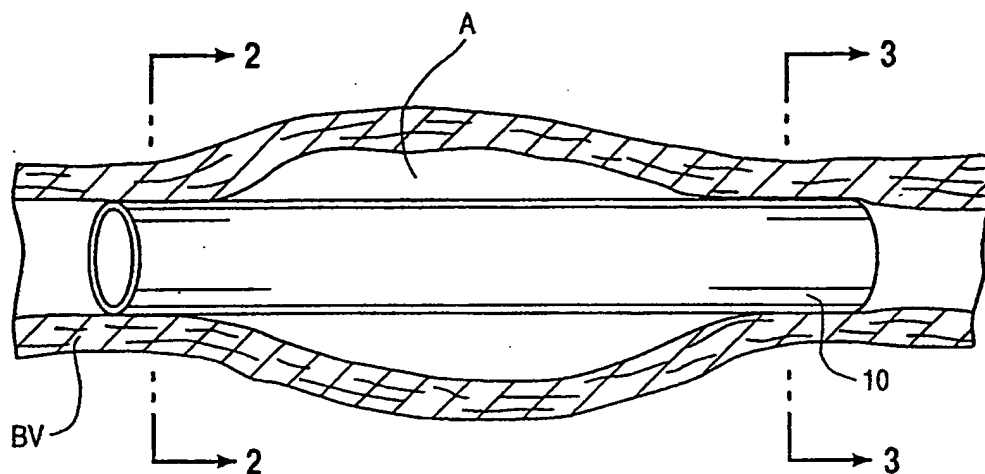


FIG. 1 (PRIOR ART)

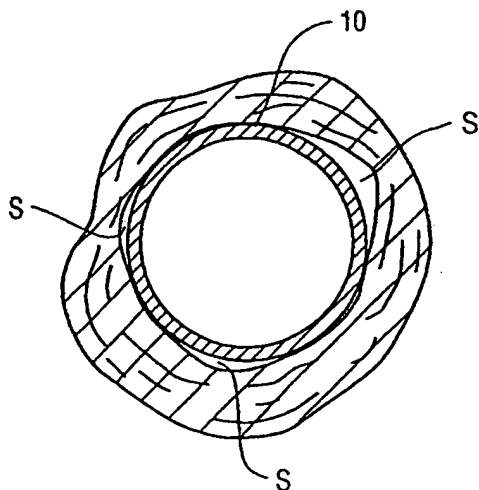


FIG. 2 (PRIOR ART)

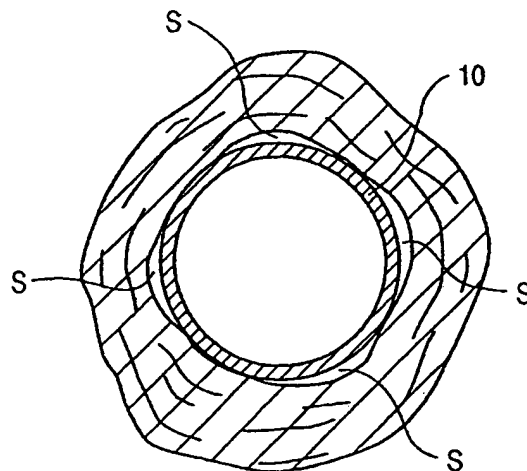


FIG. 3 (PRIOR ART)

2 / 12

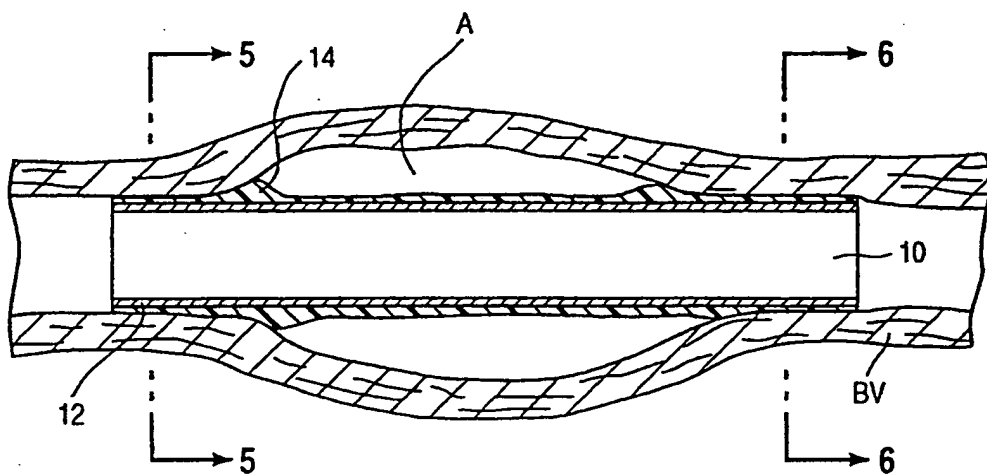


FIG. 4

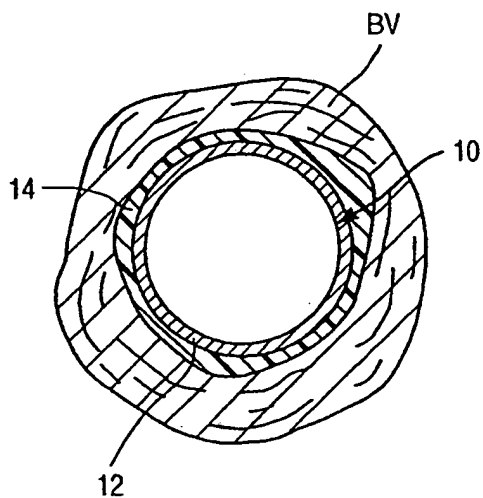


FIG. 5

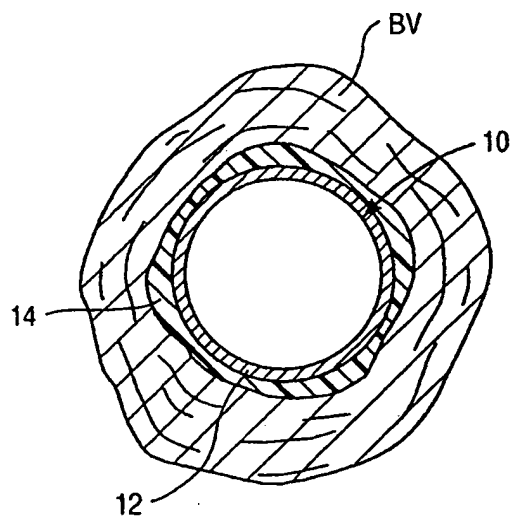


FIG. 6

3/12

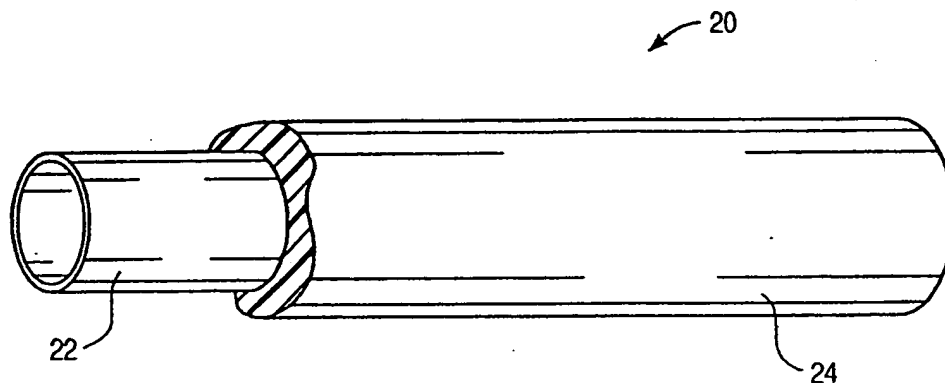


FIG. 7

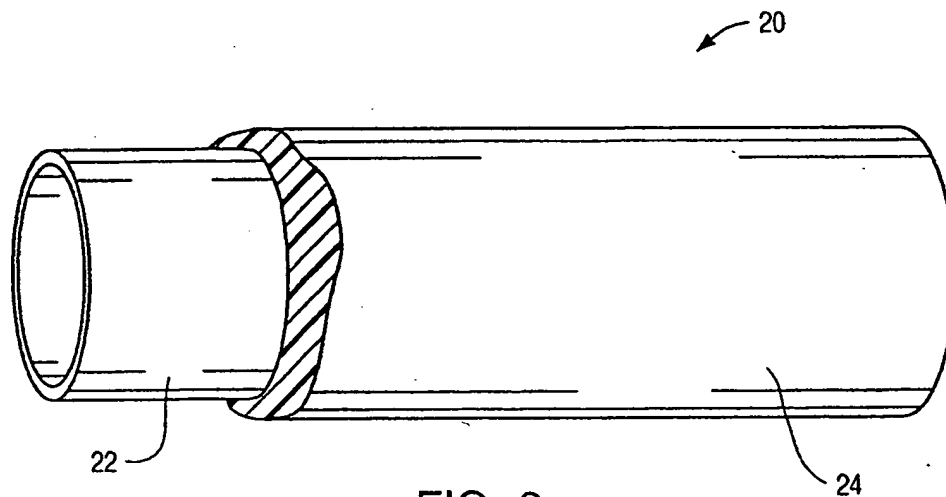


FIG. 8

4 / 12

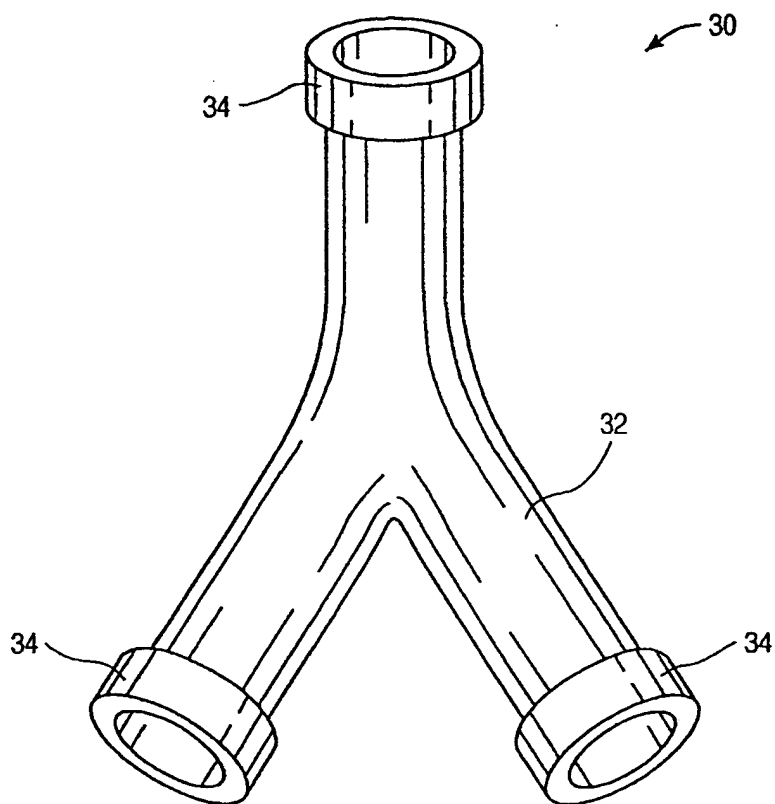


FIG. 9

5/12

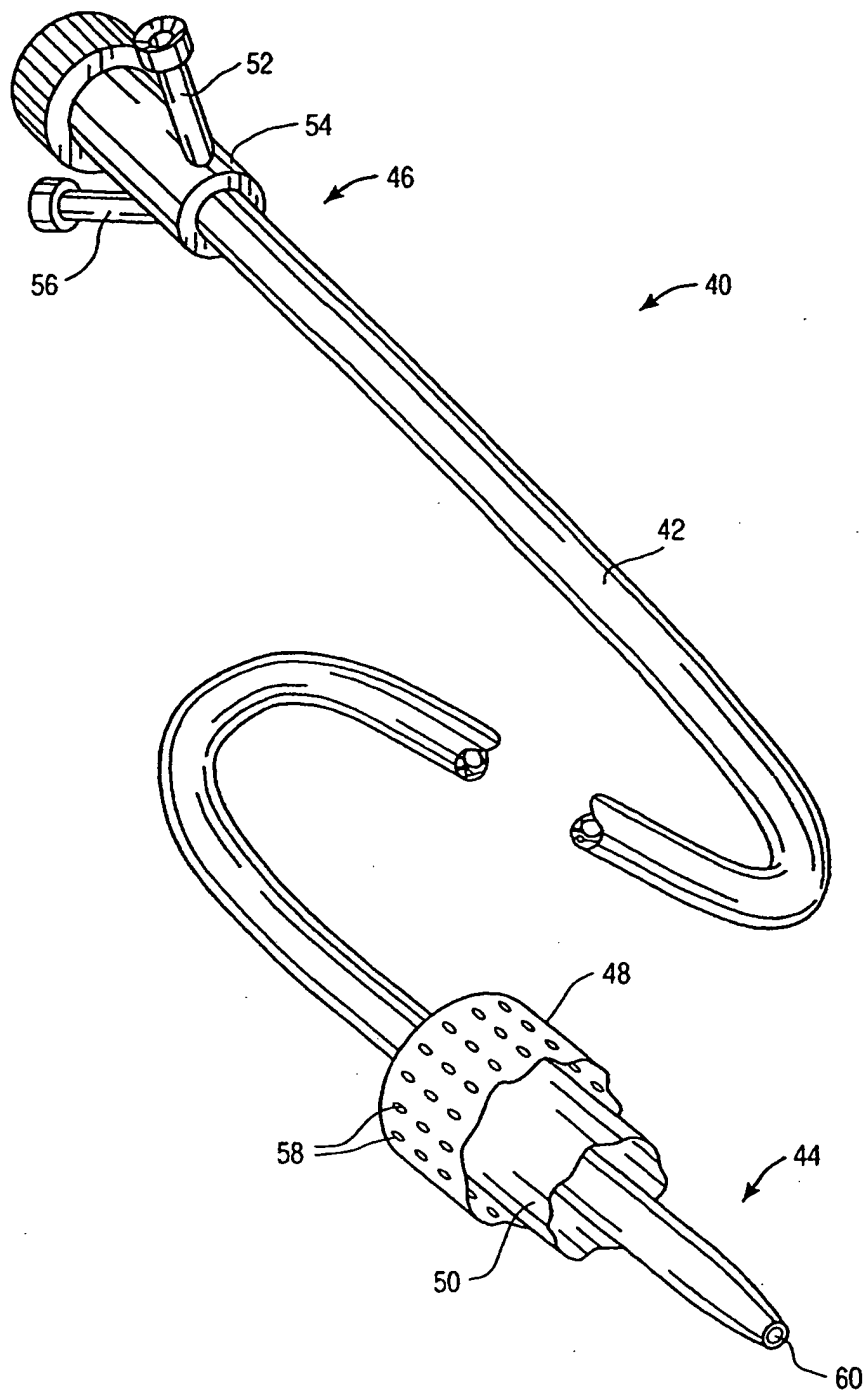


FIG. 10

6/12

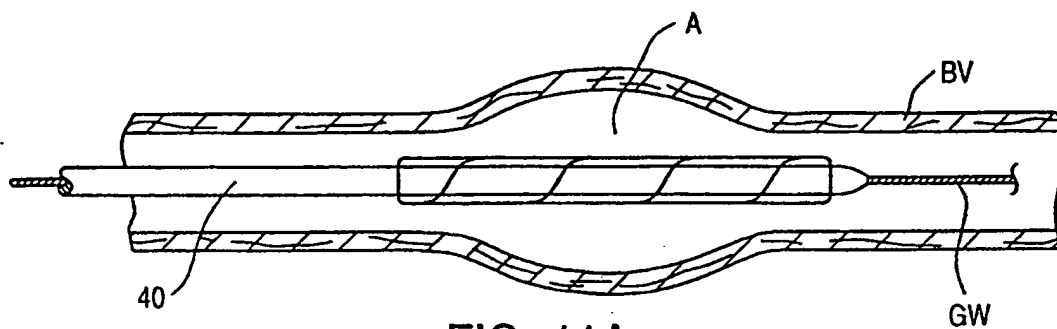


FIG. 11A

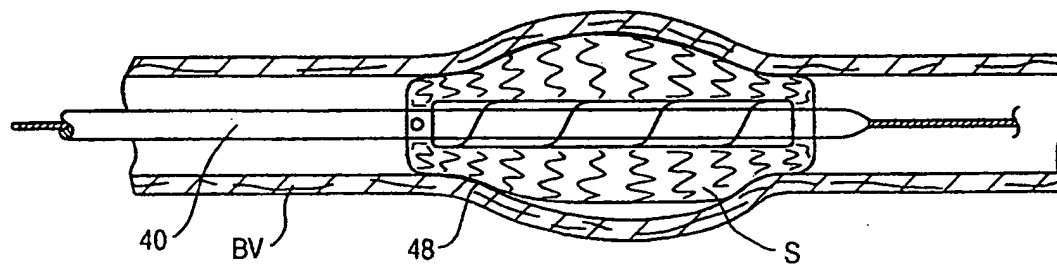


FIG. 11B

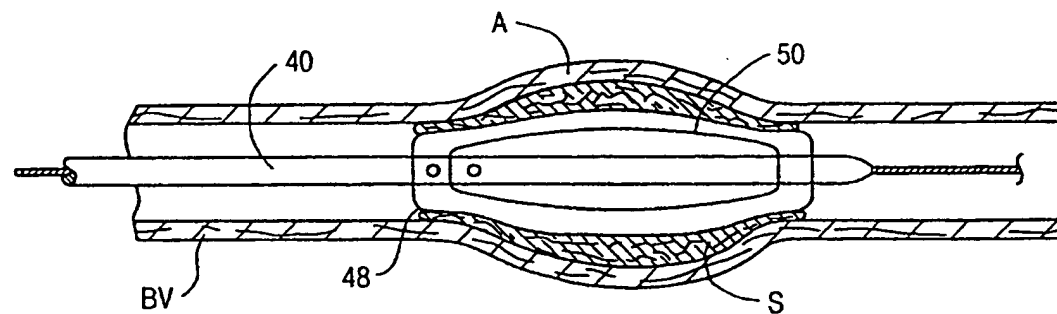


FIG. 11C

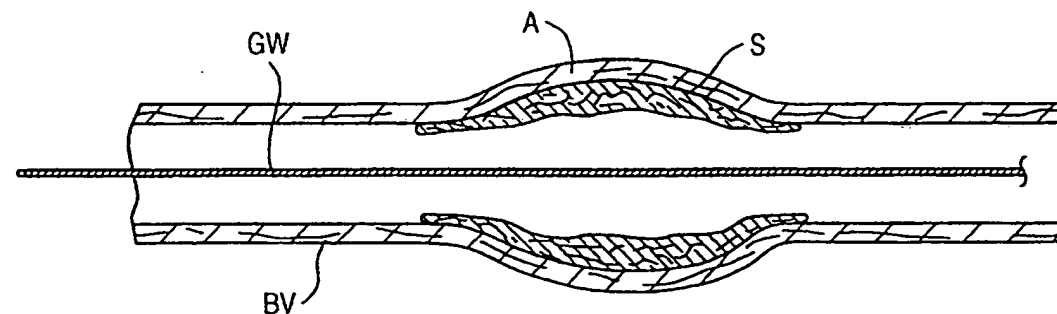


FIG. 11D

7/12

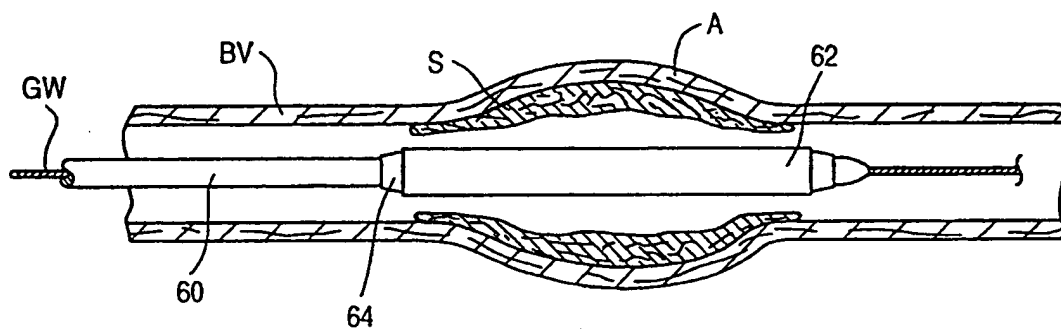


FIG. 11E

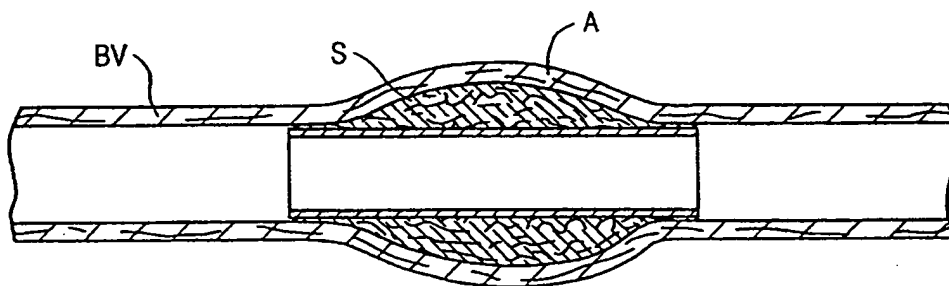


FIG. 11F

8 / 12

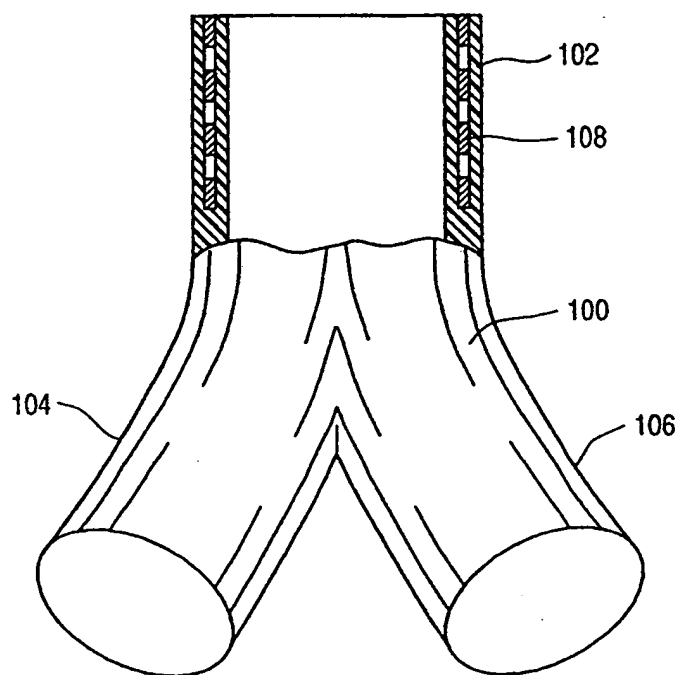


FIG. 12

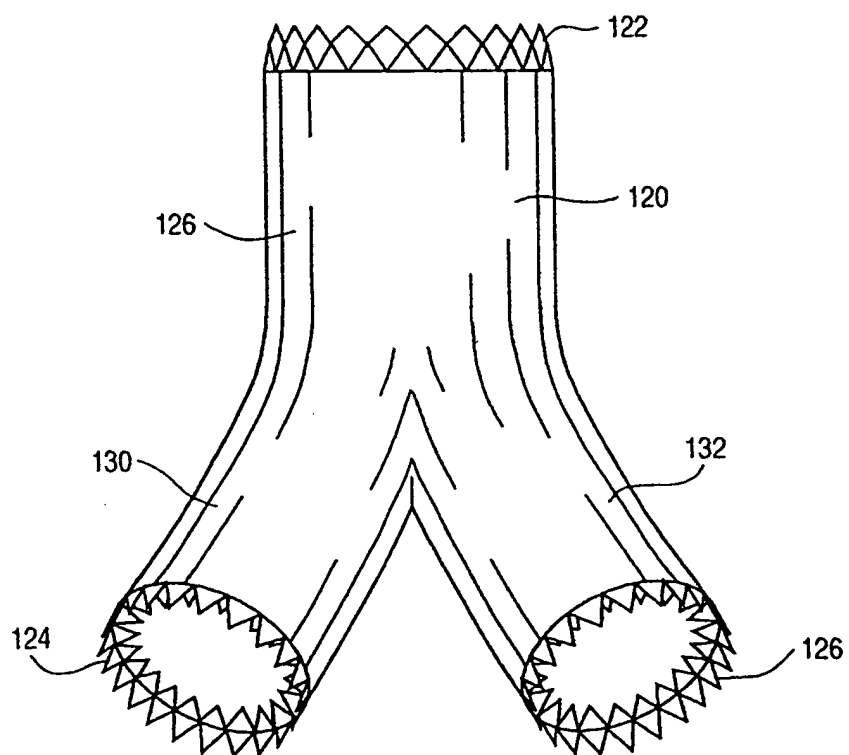


FIG. 13

9/12

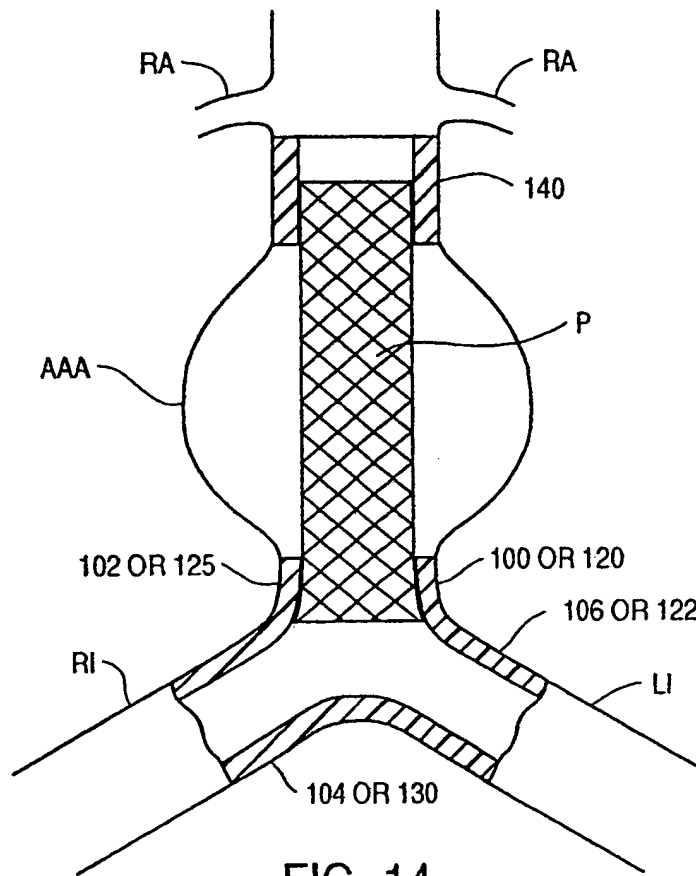


FIG. 14

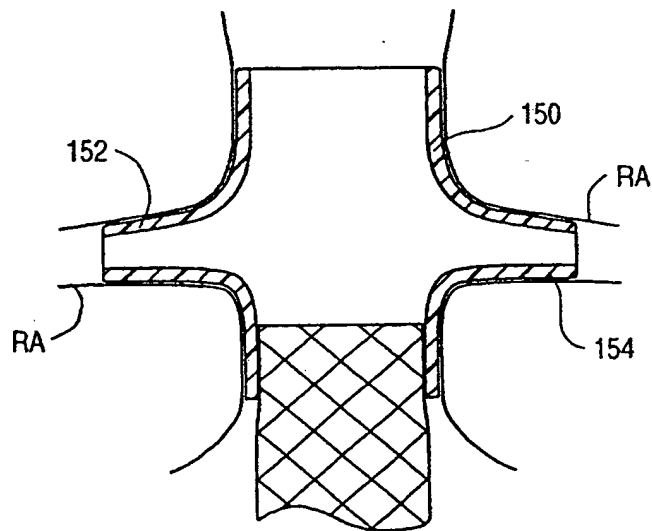


FIG. 15

10 / 12

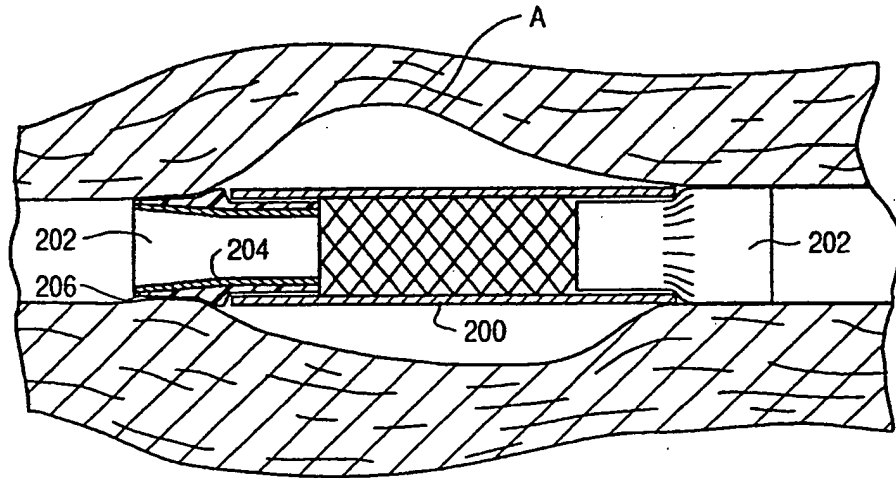


FIG. 16

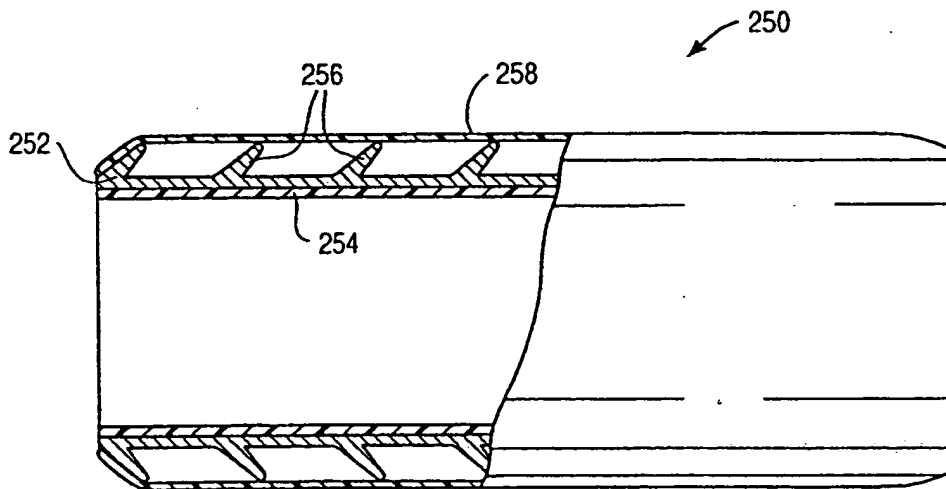


FIG. 17

11 / 12

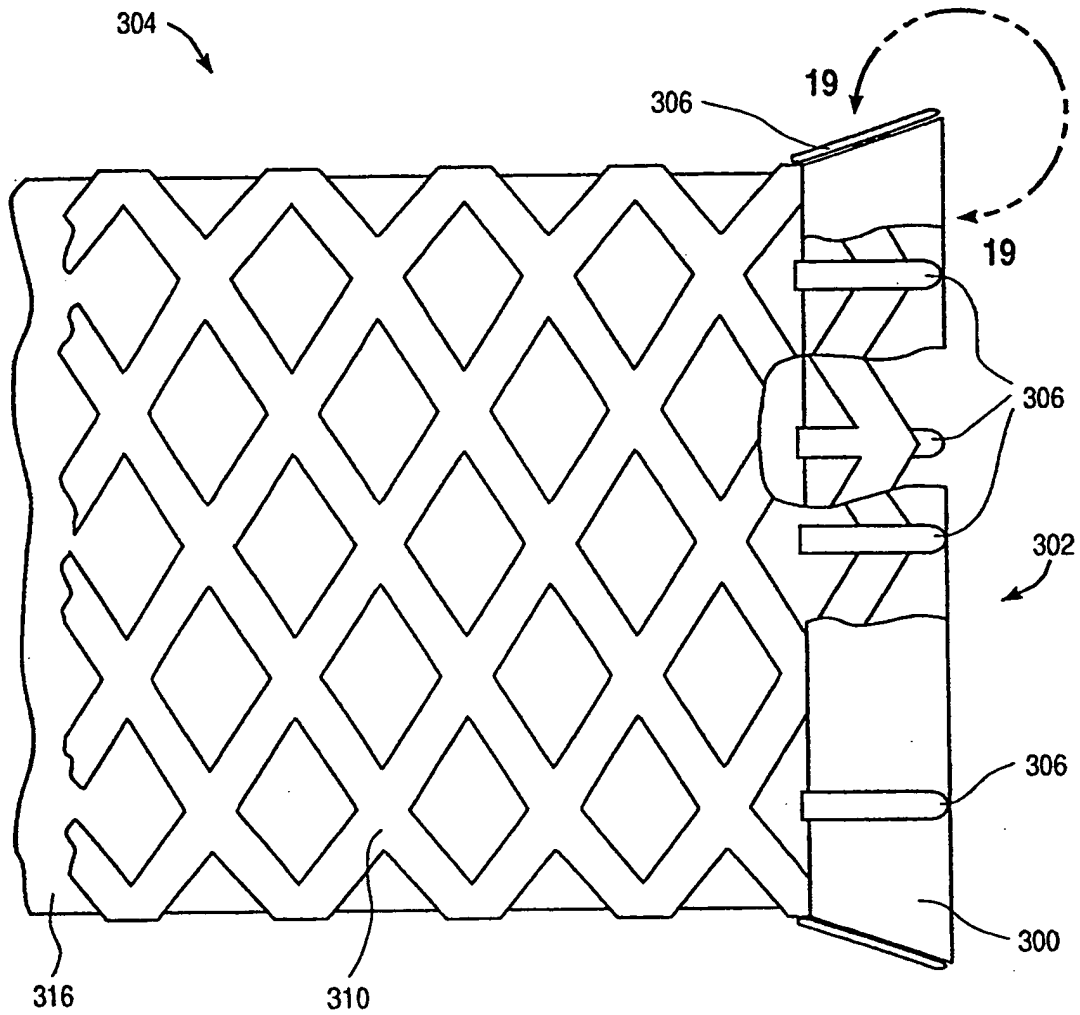


FIG. 18

12 / 12

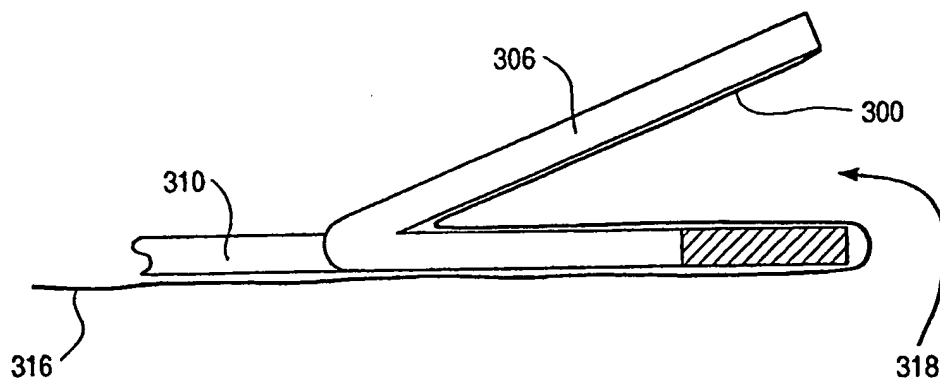


FIG. 19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/14281

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06; A61M 29/00

US CL :604/96; 623/1, 12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/36; 604/96; 606/151-158, 191-200; 623/1, 11, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 5,100,429 A (SINOFSKY et al) 31 March 1992, col. 8, line 16 to col. 9, line 5.	1-3, 5, 6, 8, 9, 15-18, 20-27, 29-31 4, 10-14, 28
A	US 4,636,213 A (PAKIAM) 13 January 1987, col. 5, lines 15 and 16.	7, 19
X	US 5,334,201 A (COWAN) 02 August 1994, col. 3, line 49 to col. 4, line 60.	1-3, 5, 6, 8, 9, 15-18, 20, 21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"A" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

22 DECEMBER 1996

Date of mailing of the international search report

21 JAN 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3590

Authorized officer

FOR
DEBRA S. BRITTINGHAM

Telephone No. (703) 308-3401